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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/608,978

06/26/2003

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EXAMINER

JOHNSON III, HENRY M

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

03/27/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/608,978	<b>Applicant(s)</b> DOBAK ET AL.	
	<b>Examiner</b> Henry M. Johnson, III	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### ***Response to Arguments***

Applicant's arguments filed March 19, 2008 have been fully considered and are persuasive. All previous rejections are withdrawn and the finality of the last office action is withdrawn.

Upon further search and consideration, new grounds of rejection are provided herein based on multiple teachings. Balloon catheters are pervasive in the art with varying intended uses. Lumens for inflating balloons are common, as are supply and return lumens when used for circulating a cooling medium. Lumens for a guidewires are also pervasive in the art. The examiner takes the position that with the plethora of art, a skilled artisan would look at the prior teachings and select the device structure suited for the intended use of the catheter.

### ***Claim Rejections - 35 USC § 103***

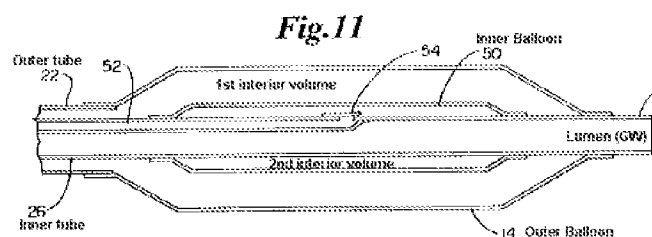
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,968,069 to Dusbabek et al. in view of U.S. Patent 4,445,892 to Hussein et al. Dusbabek et al. disclose a catheter with inner and outer balloons at a distal end (Fig. 11, #s 14 & 50) arranged with inner and outer tube structures. Both balloons are attached to the distal



most portion of the inner tube and the proximal portion of the inner balloon also attached to the inner tube. The proximal portion of the outer tube is attached to the outer tube. Volumes are disclosed

between the inner balloon and the inner tube and between the dual balloons. Lumens are provided to communicate with interior volumes and a central lumen which is interpreted as capable of use with a guidewire. Dusbabek et al. teach the use of marker bands (Col. 9, line 43). Dusbabek et al. do not disclose the use of spacers in the structure. Hussein et al. disclose a dual balloon catheter (abstract) with inner and outer tubes wherein spacers are provided to center the inner tube within the outer tube and allow fluid flow around the inner tube (Fig. 6, #s 308 & 310). Hussein et al. teach the use of perfluorocarbon for cooling. It would have been obvious to one skilled in the art to combine the spacers as taught by Hussein et al. in the invention of Dusbabek et al. to maintain alignment of the structure as disclosed by Hussein et al.

Claims 2-4 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,968,069 to Dusbabek et al. in view of U.S. Patent 4,445,892 to Hussein et al. as applied to claim 1 above and further in view of U.S. Patent 5,106,360 to Ishiwara et al. Dusbabek et al. and Hussein et al. are discussed above, but do not teach separate supply and return lumens. Ishiwara et al. teach a catheter device with concentric balloons defining a volume between an inner and outer balloon and between the inner balloon and a tube with

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multiple lumens (Fig. 5) in fluid connection with the volumes (Fig. 5, # 30). Each volume is provided with two lumens as is common for the circulation of a cooling fluid or refrigerant. Catheters with multiple lumens for various purposes are well known and it would have been obvious to one skilled in the art to combine the teachings of Dusbabek et al., Ishiwara et al. and Hussein et al. to create a dual balloon catheter with cooling/heating capability.

Regarding claims 10 and 11, the use of alternative cooling fluids is considered obvious to a skilled artisan.

If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. (See KSR [127 S Ct. at 1739]).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,968,069 to Dusbabek et al. in view of U.S. Patent 4,445,892 to Hussein et al. in view of U.S. Patent 5,106,360 to Ishiwara et al. as applied to claim 8 above and further in view of U.S. Patent 6,063,101 to Jacobsen et al. Dusbabek et al., Ishiwara et al. and Hussein et al. teach all of the limitations of the claim except a fluid contrast media. Jacobsen et al. teach that it is old and well known in the art to provide a contrast media as an inflation fluid for a balloon catheter. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a fluid contrast media in the invention of Dusbabek et al./Ishiwara et al./Hussein et al. in the fluid for inflating the balloon.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,968,069 to Dusbabek et al. in view of U.S. Patent 4,445,892 to Hussein et al. in view of

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U.S. Patent 5,106,360 to Ishiwara et al. as applied to claim 8 above and further in view of U.S. Patent 6,497,721 to Ginsburg, et al. Dusbabek et al., Ishiwara et al. and Hussein et al. are discussed above, but do not teach specific pumps for the fluid delivery. Ginsburg et al. disclose a similar device and teach that it is old and well known in the art to use a variety of different pumps to circulate the heat exchange fluid (col. 24 lines 10-14). Each of the pumps disclosed by Ginsburg et al. may be substituted one for the other. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a gear pump for fluid delivery in the invention of Dusbabek et al./Ishiwara et al./Hussein et al. particularly in view of the teaching of Ginsburg et al. that a substitution as such would be proper.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 6,156,053 teaches multiple lumens in a catheter shaft, radiopaque markers and dual balloons.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 5:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Henry M. Johnson, III/  
Primary Examiner, Art Unit 3739

/HMJ/  
3/26/2008